Pre-Application Technical Assistance Reports for the Access to Recovery Grant Program

Report on Technical Assistance to Maine

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Consultation between Walter Vogl, Ph.D., and Bob Stephenson and the State of Maine
Written Report

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Introduction and Purpose of TA

The State of Maine requested technical assistance (TA) in exploring the most cost-effective methods of drug testing, as well as drug testing protocols, for the ATR voucher program. The RFA requires such testing as the method for demonstrating abstinence and determining the successful completion of treatment. Maine hopes to reduce any unnecessary costs of the drug testing to make as much funding as possible available for treatment. Hal Krause, CSAT's Project Director for Pre-Application TA for the ATR program, arranged for two experts from CSAP's Division of Workplace Programs to assist Maine with drug testing cost issues—Walter Vogl, Ph.D., the Division's expert on toxicology, and Bob Stephenson, Director of the Workplace Programs Division.

Methodology

The TA took place by telephone on May 11, 2004. The TA was informal and entailed the discussion of questions related to the issues identified in the Purpose of the TA. Participants from CSAT included the two experts (Dr. Walter Vogl and Bob Stephenson), as well as Hal Krause, Andrea Kopstein, Ph.D., Ed Craft, Dr. P.H., and Ruby Neville. Kimberly Johnson, Director of the State's Office of Substance Abuse, represented Maine, and contractor participants included Kazi Ahmed, Ph.D., Mary Hayes, and Pat Kassebaum from Johnson, Bassin & Shaw, Inc. (JBS) and Susan Heil, Ph.D., from AIR. (For the background and experience of the CSAP experts, see the last section of this report.)

The notes summarized in this report are paraphrased and not verbatim.

Content of TA Discussion

Issue #1: Cost-effective alternative methods of drug testing

Maine: Are there alternative methods of drug testing that would be equally accurate, but more cost-effective, than urine testing? Maine currently uses urine testing only for our drug courts and, based on this experience, have found such testing to be costly, intrusive, and difficult to perform if the only staff person available is of the opposite sex. In the drug courts, Maine is using on-site urine screening and is encountering a number of false-positive results, as well as many cases in which offenders report that they have not used drugs and therefore the positive urine test result must be in error. These issues trigger confirmation tests, which cost about $200

per test.

Dr. Vogl: The Division has been studying alternative testing methods for about 6 years and is currently incorporating hair and fluid testing into the workplace testing program. The proposed guidelines have been released and are now out for public comment. Let me summarize the advantages and shortcomings of several alternative testing methods:

- **Saliva (oral fluids):** We feel that oral fluids are fairly comparable to urine tests in terms of their short [1- to 2-day] window of detection, although oral fluids have a somewhat shorter window for several drugs. Because of this shorter window, treatment programs would probably want to do oral screens more frequently than urine screens or they could do a combination of urine and oral screens. Oral fluid testing offers several advantages: (1) it is the least invasive method from the privacy perspective, eliminating the need for same-sex observation; (2) the opportunity to tamper with the specimen is almost non-existent, since the collector of the sample is participating actively; (3) few products are yet available on the Internet that can be used to interfere with an oral sample, whereas the number of products sold to adulterate urine screens has increased significantly; and (4) the cost is probably comparable, or possibly even lower, than urine screens. Few laboratories now do this type of testing, but if oral fluid testing becomes a part of workplace testing programs, then this method will become much more common and we expect costs to go down.

- **Hair:** We expect hair to be a useful method for testing the history of a person's drug use over time, rather than for short-term treatment compliance. Hair is the method with the largest window of detection. Practically, the focus is on the first 1½" of hair from the scalp out, which shows drug use within the past 90 days. Theoretically, a 6" segment of hair would show use over 1 year. A disadvantage is that people worry about having a chunk of their hair cut out.

- **Sweat:** Sweat testing is being primarily used in the criminal justice system to track those on parole or house arrest, and this method seems to work quite well. Sweat testing involves affixing a patch, rather like a band-aid, to be worn for 3 to 7 days. The window of detection applies to a drug taken within 24 hours before the patch is applied and throughout the period of wearing the patch. This patch cannot be tampered with, but it becomes an irritant and seems invasive after several days. Some people are allergic to adhesives. An advantage compared to urine testing is its longer window of detection.

Consultant recommendation: Either urine or saliva screening would be cost-effective in testing for treatment compliance. Selecting urine screens now would not prevent a treatment program from switching later to oral testing as more laboratories do this testing and as the cost comes down.

Issue #2: RFA requirements for testing

Maine: It appears that the RFA requires urine testing rather than any other method. Can we consider other kinds of analyses, such as oral fluids testing?

Andrea Kopstein, Ph.D.: Yes, other methods are fine. We just need some proof of abstinence.

Issue #3: On-site testing vs. laboratory testing

Maine: *Will you please address how to balance on-site vs. laboratory testing in terms of the*

accuracy of the tests, their ease of collection, and the cost? For our drug courts, we use "dip sticks" for on-site testing. They're cheap, but they don't appear to be all that accurate and there are collection issues. We wind up with many false negatives and false positives, and then have to send them to the lab for further testing using mass spectrometry, which is a huge expense.

Dr Vogl: Let's look at five issues here: (1) How accurate are the on-site test kits; (2) What are the costs of on-site vs. laboratory testing; (3) Does on-site testing have an advantage in terms of rapid results; (4) Will the on-site kits be flexible enough regarding individual drug use; and (5) Are there sources that reliably evaluate kits available on the Internet?

(1) ***Accuracy of on-site test kits.*** In the workplace program, we have seen improvements in on-site test kits over the past few years, and we expect to see those improvements continue. We may propose to include on-site testing in the workplace program. We do further evaluation of on-site devices after they have been cleared by the Food and Drug Administration (FDA). The FDA is responsible for clearing these types of devices, but they only assess whether the device meets the performance levels stated by the manufacturer. The package inserts in the test kit will detail the data that the manufacturer provides. However, this FDA evaluation does not assure that the device will meet workplace testing standards. In a workplace environment, cut-off levels [for a positive reading] need to be high enough to avoid unintentional false positives whenever possible, since a misreading may affect a person's livelihood forever.

In about 1 year, the CSAP Division of Workplace Programs will have test results concerning on-site kits, since we will be doing compliance monitoring on actual numbers. At that point, treatment programs could shift to those kits or use them for certain kinds of drug classes or circumstances.

Information about CSAP's workplace testing program is available at the Web site *www.workplace.SAMHSA.gov.*

(2) ***Costs of on-site vs. laboratory testing.*** For urine testing, on-site and laboratory testing is comparable in cost. Most on-site testing devices cost in the $10-$15 range for a 5-drug panel and $3-$4 for a single drug. However, if the on-site testing gives a presumptive positive, you will still have to send the screen to a laboratory for confirmation.

(3) ***Rapidity of results.*** The time elapsed between collecting specimens and the laboratories' reporting of results has been getting shorter. The time difference between on-site and laboratory testing is not really significant, except for industries that are doing on-the-spot "fitness for duty" tests. Laboratories will generally screen within 1 day. If the screen is positive, then it will take 2 more days to do a confirmatory test.

(4) ***Flexibility regarding drugs being tested.*** One disadvantage of the test kits may be their inability to test particular drugs on an individual basis. The different kits test for different drugs, which could add confusion and cost. For example, Maine stated that its programs would screen for and then treat clients as necessary when they have a history of using oxycodone (Oxycontin) or generic opiates. Only clients with a history of such use would be tested for these substances, and this could require a special test kit.

(5) ***Resources that evaluate on-site kits.*** Both CSAP and the Administrative Office of the U.S. Courts have done studies of on-site kits in the past 4-6 years, but the kits have changed so much that those study results are probably invalid. Some manufacturers support and publish studies of their kits; the best source for these studies is the *Journal of Analytic Toxicology.* The Administrative Office of the U.S. Courts also may maintain a list of the approved on-site kits that their judicial districts can use. In addition, laboratories are getting specimens from on-site testing kits and doing confirmations of their presumptive tests; a laboratory doing such tests may be willing to share their results concerning what they are finding under different drug classes.

Maine: *Is it even worth it to have an on-site test kit? Given our volume of tests, perhaps the best choice is to negotiate and contract with a laboratory for a reasonable cost to do statewide testing?*

Dr. Vogl: Workplace testing programs have been around for some time, so you should have a good choice of approved laboratories that know what they're doing. I believe that you would probably get the most for your money through a lab-based program. You should be able to get a good price and good results. Use overnight express to ship your specimens to the lab so they arrive the next day. The specimens can be quickly screened and, if results are negative, they can be reported out to you electronically.

Bob Stephenson: Using a laboratory is a protection for everybody. Unless the program has extraordinarily good [on-site testing] technology, and staff who are well trained to do stable testing on-site, a program will be better off sending specimens to a laboratory. The lab can take care of the chain of custody and control and accessioning issues, as well as doing confirmation tests if necessary.

Issue #4: Considerations with laboratory testing

Maine: *What issues might be considered in working with a laboratory regarding testing for success of a treatment program?*

Consultants: Some of the issues to consider would be (1) negotiating the costs of the screen and confirmatory tests, (2) setting appropriate cut-off levels, (3) determining what drugs to test for, (4) maintaining caution about the sensitivity of some drugs in new screening tests, and (5) looking at options regarding confirmatory tests.

(1) **Costing of the screening and confirmatory tests.** Be careful not to bundle screening costs together with the confirmation tests or total costs will be much higher. Only a percentage of screening tests will need confirmation. Until a laboratory knows what your combined screening and confirmation rate is, they will be cautious about setting their total costs if the two types of tests are bundled together.

(2) **Setting appropriate cut-off levels.** The cut-offs for drug concentration levels in urine that signify use have been around for a long time. Most U.S. laboratories are certified by the Federal

government to meet workplace standards for accurate drug testing. In the workplace program, these laboratories establish high enough cut-offs to avoid mistakenly reporting the presence of drugs in urine. Laboratories use different cut-off figures for their private-sector clients. The appropriate level for cut-offs in the ATR program could be different from other types of programs, since the goal is to demonstrate low enough levels to reasonably say that clients are drug-free. For example, 15 is often used as the confirmatory cut-off point for marijuana use in workplace programs. A figure of 14 would signify a negative result. However, laboratories can generally quantify a cut-off figure down to 2, and a lower cut-off point than 15 could be appropriate as a proof of abstinence. A program could thus decrease the cut-off figure signifying use and potentially extend the window of detection. It is, however, important not to set cut-offs so low that positive results are triggered for clients on therapeutic doses of prescribed medications. Making such adjustments would require working closely with the laboratory.

(3) **Establishing what drugs to test for.** It's important that a program test clients only for drugs that they will be treating. If testing comes back positive for drugs that the program does not treat, then the evaluation of the program's effectiveness will be distorted in a negative way.

(4) **Being cautious regarding the sensitivity of some drugs in new screening tests.** Programs need to be aware that, in some new screening tests, a group of antibiotics can trigger positive test results for opiates, specifically in the area of oxycodone. Misdiagnosis is a constant challenge. A major medical journal (either the *Journal of the American Medical Association* or the *New England Journal of Medicine)* published a requirement on this; namely, that in therapeutic monitoring situations or in treatment environments, practitioners must be careful to know the patient's history and, in certain cases, should go forward with confirmatory testing to unmask false screening positives. The screening results for cocaine, marijuana, and PCP are generally rock solid. The screening results for amphetamines, methamphetamines, and opiates require more caution, because positive test results can be caused by a wide variety of factors.

Consultant's Background

Walter F. Vogl received his Ph.D. in Chemical Engineering from the University of Virginia in 1970. He was a Commissioned Officer in the Medical Service Corps, U.S. Navy, from 1971 until 1991. During his active duty, he served for 8 years as the Senior Policy Analyst in the Office of the Assistant Secretary of Defense, where he was responsible for developing and implementing the DoD regulations that pertained to drug testing programs in the military services.

Since 1991, Dr. Vogl has been working in the Division of Workplace Programs, Substance Abuse and Mental Health Services Administration. He is the project officer for the National Laboratory Certification Program. Dr. Vogl has authored the Urine Specimen Collection Handbook for Federal Workplace Drug Testing Programs and the Medical Review Officer Manual for Federal Workplace Drug Testing Programs. In addition, he is responsible for initiating and coordinating all efforts related to the revision of the Federal Drug Testing Custody and Control Form and obtaining approval from the Office of Management and Budget.